K121574

JUN 29 2012

SYNTHES®

5 510(k) Summary

Date Prepared	April 23, 2012
Submitter	Synthes (USA) 1301 Goshen Parkway West Chester, PA 19380 United States of America
Contact	Alan T. Haley haley.alan@synthes.com (484) 356-9763
Trade Name	MatrixMANDIBLE Plate and Screw System
Common Name	Bone Plate
Classification Name	Bone Plate, 21 CFR 872.4760, Product Code JEY
Predicate Devices	MatrixMANDIBLE Plate and Screw System (K063790) Synthes Mandibular Modular Fixation System (K954385)
Intended Use	The Synthes MatrixMANDIBLE plate and screw system is intended for oral, maxillofacial surgery: • Trauma • Reconstructive surgery • Orthognathic surgery (surgical correction of dentofacial deformities)

Device Description

The Synthes MatrixMANDIBLE Plate and Screw System consists of a variety of plates offered in multiple shapes and sizes and a variety of screws offered in multiple diameters and lengths to meet the anatomical needs of the patient. System implants are manufactured in either titanium or titanium alloy and are intended for single use only.

The MatrixMANDIBLE screws that are the subject of this premarket notification are made from titanium alloy (Ti-6Al-7Nb) and are available in a diameter of 2.0 mm and lengths ranging from 4 mm to 8 mm, and have a thread pitch of 0.5 mm. These screws work with all plates within the MatrixMANDIBLE Plate and Screw System.

These devices are offered non-sterile and must be sterilized prior to use. MatrixMANDIBLE screws are intended for single use.

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Technological Characteristics

The proposed MatrixMANDIBLE devices are similar to the predicate devices in terms of indications, dimensions, principles of operation, and design (i.e. cortex screws for internal fixation of bone). The non-clinical testing data discussed below show that the subject devices have equivalent or better mechanical performance when compared to the predicate devices and that the minor differences in device geometry do not raise new issues of safety and effectiveness.

Clinical Testing

No clinical testing was performed to support this submission.

Non-Clinical Testing

Mechanical testing was performed to compare the proposed devices to the predicates to measure:

- Strip-out resistance (N·m)
- Pull-out strength (N·m)
- Yield Torque (N·m)
- Insertion Torque (N·m)
- Insertion Factor of Safety

The non-clinical test results demonstrate that the mechanical performance of the proposed Synthes MatrixMANDIBLE screws is equivalent to or better than the predicate devices and support the substantial equivalence to the predicate devices.

Substantial Equivalence to Predicate Devices

In conclusion, the proposed Synthes MatrixMANDIBLE Plate and Screw System devices have the same intended use as, and technological characteristics similar to, the legally marketed predicate devices. Non-clinical testing data demonstrate that differences in the technological characteristics do not affect safety or effectiveness. The information presented supports substantial equivalence of the proposed devices to the predicate devices.

(end of summary)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Alan T. Haley
Regulatory Affairs Specialist
Synthes, Incorporated
1301 Goshen Parkway
West Chester, Pennsylvania 19380

JUN 29 2012

Re: K121574
Trade/Device Name: MatrixMANDIBLE Plate and Screw System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: May 25, 2012
Received: May 30, 2012

Dear Mr. Haley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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4 Indications for Use Statement

510(k) Number (if known): _____

Device Name: MatrixMANDIBLE Plate and Screw System

Indications for Use: The Synthes MatrixMANDIBLE plate and screw system is intended for oral, maxillofacial surgery:

- Trauma
- Reconstructive surgery
- Orthognathic surgery (surgical correction of dentofacial deformities)

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use_____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K121574